

- 6 -

Appl. No. 09/866,261

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 2, 6, 7, 13, 15 and 17 are pending in the application, with claims 1, 6, 13 and 15 being the independent claims.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Objection to the Specification***

The status of the non-provisional parent application has been updated, as required by the Examiner.

***Rejections under 35 U.S.C. § 112***

Claims 6, 7, 13, 15 and 17 are rejected under 35 U.S.C. § 112, ¶ 2, as being indefinite, because the preamble contains the phrase the “subgroup specificity of the nucleic acid of naturally occurring avian leucosis/sarcoma virus,” as being unclear in what the phrase intends to achieve. The Examiner interprets this claim to mean “distinguishing between the different subgroup of avian leucosis/sarcoma virus.” (Office Action at p. 3).

Claim 13 does not contain this objected phrase. Concerning claims 6, 7, 15 and 17, Applicant respectfully directs the Examiner’s attention to the prosecution in the parent non-provisional application. In that earlier case, in response to a rejection in paper number 6 to claims 1, 6, 11-16 that the term “at the nucleic acid level” was confusing, in response Applicant amended claims 6, 15 and 16 in an amendment, paper number 7, to add precisely this objected term. In the subsequent Office Action, paper number 9, these same claims were

- 7 -

Appl. No. 09/866,261

allowed with this objected term. Applicant hereby specifically incorporates by reference paper numbers 6, 7 and 9, and the arguments, amendments and statements contained therein. Hence, Applicant respectfully requests that this rejection be withdrawn, in view of the prosecution in the parent non-provisional case.

Claims 13, 15 and 17 are further rejected 35 U.S.C. § 112, ¶ 2, because it is unclear to the Examiner what the phrase or element "an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp<sup>env</sup> 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b)" embraces.

Again, this element was added in an amendment, paper number 8, the parent non-provisional case in response to a rejection in the Office Action, paper number 7. This element was accepted and these claims were allowed in a subsequent Office Action, paper number 9. Applicant hereby specifically incorporates by reference paper numbers 6, 7 and 9, and the arguments, amendments and statements contained therein. Hence, Applicant respectfully requests that this rejection be withdrawn, in view of the prosecution in the parent non-provisional case.

Claims 13, 15 and 17 are also rejected under 35 U.S.C. § 112, ¶ 1, for lack of written description. The Examiner states that the same limitation "an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp<sup>env</sup> 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b)" is not described in the specification. More specifically, the Examiner states that this limitation embraces a genus of nucleotide sequence encoding the

- 8 -

Appl. No. 09/866,261

gp<sup>env</sup> 85 protein, but the specification has not disclosed a representative number of species within this genus.

Applicant respectfully traverses this rejection. The specification fully describes the relevant species in Table 1 on page 28, from page 34-line 6 to page 35-line 4 (paras. 71 and 72 in corresponding publication no. 2005/0042591 A1), from page 39-line 4 to page 39-line 20 (Id. at para. 78), and from page 44-line 4 to page 45-line 6 (Id. at paras. 84-85), among others. Hence, this rejection should be withdrawn.

Claims 6, 7, 15 and 17 are also rejected under 35 U.S.C. § 112, ¶ 1, for a lack of enablement for a method of determining the subgroup of specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus, wherein the subgroup is J. The Examiner also suggested that these claims be amended to limit the scope to subgroups A-E. The Examiner's suggestion is greatly appreciated. Claims 6 and 15 have been so-amended and claims 7 and 17 depend on claim 6. Hence, Applicant believes that this rejection has been overcome.

#### *Rejections under 35 U.S.C. § 103*

Claims 1, 2 and 13 are rejected under 35 U.S.C. § 103(a) for being unpatentable over Hauptli et al. (Journal of Virological Methods, 1997, vol. 66, pages 71-81) in view of Spencer et al. (Avian Disease, 1977, vol. 21, no.3) and Boshinski et al. (U.S. Patent No. 5, 976, 873).

Applicant respectfully traverses this rejection. Hauptli et al. disclose a method of detecting the presence of avian leucosis virus, said method comprising the steps of:

- (a) isolating viral RNA from allantoic fluids of SPF eggs;
- (b) RT-PCR using primer pairs ALVgp85U3/L3
- (c) Detecting the presence of the virus using restriction endonuclease analysis (page 77).

- 9 -

Appl. No. 09/866,261

(emphasis supplied).

Restriction enzyme (endonuclease) includes any enzyme that recognizes and cleaves a specific short sequence, the restriction site, in double-stranded DNA molecules. These enzymes are widespread in bacteria and are used extensively in recombinant DNA technology. See Molecular and Cell Biology, Harvey Lodish, Arnold Berk, S. Lawrence Zipursky, Paul Matsudaira, David Baltimore, James Darnell, Fourth Edition, W.H. Freeman and Company 41 Madison Avenue New York, NY 10010 (relevant excerpts are attached hereto). This procedure could involve the introduction of bacterial genetics into the sample, additionally running the cleaved amplification products out onto the gel for determining of different subgroups of avian leucosis/sarcoma retroviruses does not give the specific characterization of the avian leucosis/sarcoma retroviruses subgroups, nor does it provide a means of determining the viral variance at the genetic level.

Whereas, in the present invention detection of avian leucosis virus in albumen of chicken eggs using reverse transcription polymerase chain reaction. The procedure involves the following:

1. isolation of the naturally occurring avian leucosis/sarcoma retroviruses the albumen of chicken eggs.
2. performing RT-PCR with the specified primers [PA1/PA2 (for subgroup A, PU1/PU2 (for subgroup A, B,C,D, E), PA10/PA20 (for subgroup A), PB1/PB2 (for subgroup B), PC1/PC2 (for subgroup C), PD1/PD2 (for subgroup D), PE1/PE2 (for subgroup E)].
3. direct sequencing to the RT-PCR product.

"Operationally, the three steps would take a total of 3 days, with distinct advantages over tissue culture/IFA methods that require about 2 weeks for ALV subgroup identification."

- 10 -

Appl. No. 09/866,261

Pham et. al. (Journal of Virological Methods, 1999, vol. 78, pages 1-11, and Thuy D. Pham (Molecular Epidemiology of Avian Leukosis/Sarcoma Retroviruses in Chicken Eggs, copyright 1997, UMI). The methods of viral detection of claims 1 and 13 are patentably distinct from the restriction endonuclease analysis as suggested by Hauptli et al., because it does not introduce various endonucleases into the system to cut the retroviral DNA. Neither Spencer nor Boshinski remedy this deficiency in Hauptli, and therefore a hypothetical combination of Hauptli, Spencer and Boshinski does have the limitations of claims 1 and 13, as amended, and claims 1 and 13 are patentable over this hypothetical combination. Claim 2 depends on claim 1 and recites limitation therefrom, and is therefore also patentable.

Claims 6, 7, 15 and 17 are rejected under 35 U.S.C. § 103(a) for being unpatentable over a four-way combination of Hauptli et al. in view of Spencer et al. and Boshinski et al., and in further view of Bova et al. (Journal of Virology, 1988, vol. 62, no. 1, pages 75-83.)

For substantially the same reasons that amended claims 1 and 13 are patentable over the hypothetical combination of Hauptli, Spencer, and Boshinski, independent claims 6 and 15 are patentable over this combination and Bova. Applicant notes that both independent claims 6 and 15 recite a "sequencing the amplified RT-PCR product" step missing in Hauptli, and Bova does not remedy this deficiency.

Hence independent claims 6 and 15 are patentable over the cited combination. Claims 7 and 17 are dependent on claim 6 and cited further limitations therefrom and are also patentable over the cited art.

### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the

- 11 -

Appl. No. 09/866,261

Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

**The H.T. Than Law Group**



H.T. Than  
Attorney for Applicant  
Registration No. 38,632

Date: July 15, 2005

Waterfront Center  
1010 Wisconsin Ave., NW, Suite 560  
Washington, D.C. 20007  
(202) 363-2620